(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: 0 654 250 A1

(12) EUROPEAN PATENT APPLICATION

(21) Application number: 94307507.7

(51) Int. Cl.[6]: A61B 17/68

(22) Date of filing: 13.10.94

(30) Priority: 19.11.93 US 155936

(43) Date of publication of application:
24.05.95 Bulletin 95/21

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IE IT LI LU MC NL PT SE

(71) Applicant: Leibinger GmbH
Bötzinger Strasse 41
D-79111 Freiburg (DE)

(72) Inventor: Reisberg, Erhard
Codazzistrasse 1
D-79346 Endingen (DE)

(74) Representative: Jackson, Peter Arthur
GILL JENNINGS & EVERY
Broadgate House
7 Eldon Street
London EC2M 7LH (GB)

(54) Form-fitting mesh implant

(57) A mesh grid implant of titanium or other biocompatible material having a plurality of orifice plate sections (40,42) that accept bone screws and having connecting arms (44) coupling each orifice plate section (40,42) with each adjacent orifice plate section (40,42). The length of the arm (44) and the included angle (46) may be set to determine the flexibility of the mesh grid. The arms (44) allow the mesh to cover not only flat bone segments but also to conform to curved, concave, and convex bone surfaces.

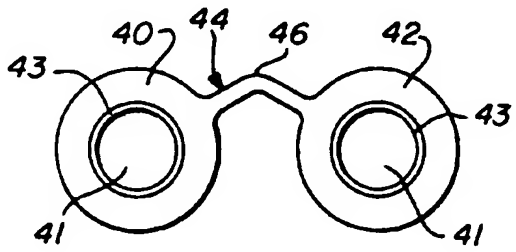

FIG. 3

EP 0 654 250 A1

The present invention relates to a form-fitting mesh implant for the fixation and immobilization of bone fragments at one or more bone fracture sites.

When there is a traumatic disruption of the continuity of a bone, it must be set such that there is no relative motion of the bone fragments at the fracture site during the healing process. If there is such relative movement, surrounding tissues are irritated thus causing pain and requiring the time fracture healing to be extended. Thus proper fixation and immobilization of bone fragments require an implant that can be moulded or formed in substantially three dimensions in many cases, which is extremely difficult to accomplish. According to currently used techniques, if a mesh implant is used to cover the area of a lost craniotomy bone flap, the mesh, when formed or shaped, develops sides that overlap, turn upwardly, or create folds. Thus the current mesh systems overlap or curl when the mesh implant is shaped three dimensionally in order to adapt to a curved shape because the connecting arms, that connect plate sections having orifices therein for receiving a bone screw, cannot be expanded and those at the outer edge cannot be compressed a sufficient degree necessary to form a relatively smooth surface. Thus the overlapping edges and raised areas can cause lacerations of the overlying tissue at can result in infections.

Further, in the currently used techniques, reconstruction of the eye socket, including orbital walls, floor, and roof, is achieved with bone and alloplastic materials such as titanium plate implants to repair the defect. As an example, regular meshes or grid plates can be introduced and secured to the orbital rim with bone screws. Because of the variable radius of the eye sockets, a standard preformed implant usually will not fit precisely. The surgeon's task is to manually form the mesh implant so that the bone defect is covered in a manner such that the mesh material is formed to fit the original three-dimensional curvature of the bone. This is not achievable with conventional metal plate implants except to a limited extent with a grid plate that has separate sections or flaps that can be bent as a total section.

Another method of fitting metal mesh plates or sheets to the convex skull shape is by cutting out wedges in the outer section of the plate to avoid overlapping sections when the plate is formed into a convex shape. This process is difficult and time-consuming, and usually must be performed by the manufacturer prior to the operation.

It is an object of the present invention to provide a form-fitting mesh implant that can be contoured to a concave or convex anatomical shape at the time of use of the mesh implant with the use of arms connecting spaced orifice plate sections that allow the connecting arms to be stretched or compressed as needed to form the desired anatomical shape.

According to the present invention a form-fitting mesh implant, for the fixation and immobilization of bone fragments at one or more bone fracture sites, comprises a mesh of titanium or other biocompatible metallic material having at least two plate sections with an orifice in each plate section for receiving a bone screw; and at least one arm connecting the two plate sections, the arm having at least two arm sections connected at a bend such that the arm can be selectively compressed, stretched, and contoured primarily by deformation at the bend to fix bone fragments in a particular anatomical shape.

The new implant has connecting arms between the plate sections having the orifices for receiving the bone screws. The arms including the bend(s) not only allow a surgeon to cover flat bone segments but also allow the surgeon to conform the mesh to curved bone surfaces, including concave, convex, or spherical surfaces for which the middle part of the mesh plate must be expanded significantly while the edges of the mesh plate are not expanded or may even be compressed. The bend in the connecting arms allows them to be stretched to a much greater degree than a regular straight connecting arm of similar dimensions and strengths. The bend also allows the mesh to be compressed without creating overlapping or raised areas which is useful when the implant is used to cover the area of a craniotomy bone flap. The metals currently used for medical implants cannot be stretched to the degree required to shape a mesh sheet of the required thickness and strength to many of the convex and concave surfaces of the human anatomy, such as the skull. This invention creates such elasticity and formability through the design of the mesh in order to overcome the limitations of the material. The present invention allows the mesh to be contoured to a concave or convex anatomical shape by the surgeon at the time of the operation.

In addition, this contouring can be done without distorting the bone screw holes in the spaced orifice sections because of the "stretching" and "compression" capacity of the connecting arms. The bone screw may be countersunk to accept a bone screw with minimal protrusion of the screw head over the outer surface of the plate for less interference with the soft tissues covering the bone and less palpability. Thus the present invention avoids distortion of the screw holes, which is very important.

Depending on the screw hole pattern and considering the number of connecting arms, a three-dimensional level of stretching of the implant can be achieved by the use of various pressures. In one embodiment of the present invention, each orifice plate section has three substantially equally spaced connecting arms that connect to three corresponding adjacent orifice plate sections. In another embodiment of the invention, four substantially equally spaced arms connect each orifice plate section with four corresponding adjacent orifice plate sections. In still an-

other embodiment of the invention, two parallel arms connect each orifice plate section with each adjacent orifice plate section. If there are three connecting arms, the arms must be made relatively stronger than where there are four connecting arms, and the arms may be more delicately made. The cross section profile of the connecting arm is substantially even over the entire length. However, the connecting arms in the area of the bend, e.g. in the middle of the arm, may be slightly narrower in width in order that less force is needed to reach the desired final form of the implant by either compressing or expanding the arm. In other words, the connecting arms are somewhat wider at their junction with the orifice plate section and more narrow towards the middle of the arm in the area of the bend.

The smaller the included angle of the connecting arm between orifice plate sections and the longer the arm sections the easier it is to manipulate the mesh implant so as to compress or expand the mesh as needed. Conversely, the greater the included angle and the shorter the curved arm, the smaller the capability to expand and compress the arm.

In the embodiment with two parallel connecting arms between any two orifice plate sections, the mesh requires more material and requires a greater amount of force to shape it. However the exertion required to shape the mesh implant will equal the three-dimensional stability of the mesh implant in its final form.

In the accompanying drawings:

FIG. 1 is a representation of a human skull illustrating representative anatomical portions thereof that can be repaired with the mesh implant of the present invention;

FIG. 2 is a diagram of a mesh implant arrangement disclosed in a prior copending application and utilising straight connecting arms;

FIG. 3 is a diagram of a mesh implant arrangement of the present invention wherein two orifice plate sections are connected by an arm;

FIG. 4 is an illustration of an orifice plate section having four equally spaced arms extending therefrom;

FIG. 5 is a diagram of a mesh implant section of the present invention utilizing the orifice plate sections with four arms as illustrated in FIG. 4;

FIG. 6 is an illustration of another embodiment of the present invention in which two orifice plate sections are coupled by an arm that is widest at the junction of the arm with the orifice plate section and narrowest in the middle of the curved arm;

FIG. 7 is a diagram of a mesh implant arrangement using the embodiment illustrated in FIG. 6 in which each connecting arm has a middle section that is narrower than the junction of the arm with the orifice plate section;

FIG. 8 is a diagrammatic representation of still another embodiment of the present invention in which the orifice plate section has three substantially equally spaced arms extending therefrom;

FIG. 9 is an illustration of a mesh implant arrangement utilizing the orifice plate section of FIG. 8 with the three connecting arms extending therefrom;

FIG. 10 is an illustration of still another embodiment of the present invention wherein two orifice plate sections are connected by two parallel arms;

FIG. 11 is an illustration of an alternate mesh implant arrangement utilizing the embodiment of FIG. 10 wherein each orifice plate section is connected to an adjacent orifice plate section with two parallel connecting arms;

FIG. 12 is a plan view of still another embodiment of the present invention;

FIG. 13 is a cross-sectional view of the embodiment of FIG. 12;

FIG. 14 is an illustration of another embodiment of the present invention; and

FIG. 15 is an illustration of a still further embodiment of the present invention.

FIG. 1 is a representation of a skull illustrating representative areas where traumatic disruption of the continuity of bone can occur. At location 12 on the top of the skull, a fracture or bone fragment must be repaired or a gap in the bone bridged. On the left side of the skull, an area 14 around the ear must be repaired or bridged. On the outside 16 of the right eye, a bone fracture is to be repaired. The floor 18 of the left eye socket is shown as an area that can be repaired and a bone fracture or gap in the cheek bone area 20 below the left eye is also shown with the mesh implant so that it can be repaired. In all of these cases, a biocompatible metallic mesh is used for defect-bridging reconstruction of bony structures or to stabilize fractured elements and to facilitate the growing together of the bone in the affected area. These areas all have different contours and shapes and thus the mesh implant that is used must be contoured for the particular area Thus in the area 12, the mesh must have a slight spherical shape. In the area 16 around the right eye, the mesh implant must have a number of shapes including convex, concave, and slightly hemispherical. In all of these cases, the mesh implant must be shaped to conform anatomically to the area where the mesh is being used.

FIG. 2 illustrates a mesh implant disclosed in our copending US patent application Serial No. 08/004,220, filed January 11, 1993, in which the mesh 22 has orifice plates 24, 26, 28, and 30, each having an orifice 31 therein for receiving a bone screw. The orifices 24, 26, 28, and 30 are connected by straight arms 32, 34, 36, and 38 to form a substantially rectangular grid. However, other shapes are also

formed such as triangular, octagonal, and the like. However, in each case the connecting arms are straight as shown in FIG. 2. Clearly, such mesh implant could be made in whatever size or dimensions desired by extending the design shown in FIG. 2. In order to shape an implant formed of the mesh of the prior art such as that illustrated in FIG. 2, it is sometimes required to shape the mesh such that sides overlap, turn upwardly, or create folds. Such overlapping or turned up edges or folds can cause lacerations of the overlying tissue which can result in substantial pain, in infections, and in difficulty of healing.

The concept of the present invention is illustrated in FIG. 3 and comprises a mesh formed of spaced orifice plate sections 40 and 42, each of which has an orifice 41 for receiving a bone screw and wherein the orifice plate sections 40 and 42 are connected by a connecting arm 44 having an angular bend 46 substantially in the middle thereof between two substantially straight arm sections. Such bend 46 allows the two orifice plate sections 40 and 42 to be easily moved towards and away from each other without substantially deforming the connecting arm 44 except by changing the included angle 45 of the bend 46. Thus it can be stretched or compressed without overlapping or curling of the material upwardly or creating folds. The orifice plate sections 40 and 42 are countersunk at 43 to accept the bone screw with minimal protrusion of the screw head over the outer surface of the mesh plate formed therewith for less interference with the soft tissues covering the bone and less palpability. Thus by compressing or stretching arm 44, distortion of the screw holes 41 is avoided, which is very important when these meshes must be contoured to a particular anatomical structure. FIG. 4 illustrates a particular construction 48 of an orifice plate 50 having four substantially equally spaced arms 52, 54, 56, and 58 thereon.

FIG. 5 illustrates a form-fitting mesh implant grid system 60 that is constructed from the plurality of orifice plate sections 50 as illustrated in FIG. 4. Note in FIG. 5 that orifice plate section 50 is coupled with arm 52 to adjacent orifice plate section 61, to adjacent orifice plate section 62 through arm 54, to adjacent orifice plate section 64 through arm 56, and to adjacent orifice plate section 66 with arm 58. All of the other orifice plate sections illustrated in FIG. 5 are coupled in a similar manner to each other through four equally spaced arms. Such construction allows the mesh implant system 60 to be formed into various anatomical shapes by either stretching, compressing, or bending the arms to form a desired anatomical shape. Thus this mesh could be used as illustrated in FIG. 1 for any of the mesh shapes and the desired size can be cut from the mesh implant screen or grid system 60 and then can be easily shaped at the time of the operation to form the desired anatomical shape.

FIG. 6 illustrates another important embodiment of the present invention illustrating a mesh grid construction 70 wherein the first and second orifice plate sections 72 and 74 having orifices 76 therein are joined by an arm 78 having a narrower section 80 at the centre thereof than in the area where the arm 78 joins the orifice plate sections 72 and 74. This thinner section 80 allows easier shaping and moulding of a mesh implant system created with such mesh construction 70. FIG. 7 illustrates such a mesh construction 82. Thus the entire mesh construction 82 of FIG. 7 can be easily cut to a predetermined size and then moulded to assume a predetermined anatomical structure shape by stretching, compressing, and bending the arms as desired without distorting the orifices 76.

The alternate embodiment 86 illustrated in FIG. 8 includes an orifice plate section 88 having an orifice 90 and three substantially equally spaced depending arms 92, 94, and 96 that have a bend at 98, 100, and 102, respectively. The mesh grid system 104 illustrated in FIG. 9 incorporates the embodiment of FIG. 8 and illustrates each orifice plate section 88 on the interior of the mesh system 104 being coupled to each adjacent orifice 88 by an arm as illustrated. On the outer periphery of the mesh 104, the orifice plate sections are coupled only to two adjacent orifice plate sections as shown.

FIG. 10 illustrates still another embodiment 106 of the present invention in which orifice plate sections 108 and 110 are coupled to each other by parallel spaced arms 112 and 114 having bends 116 and 118 therein respectively. The use of this version in a mesh grid system or screen 120 is illustrated in FIG. 11 wherein each of the interior orifice plate sections 106 is coupled to an adjacent orifice plate section by means of a pair of parallel spaced arms as illustrated. This implant requires more material and would require a greater amount of force to shape it as opposed to the embodiments illustrated in FIG. 5, FIG. 7, and FIG. 9. However, the exertion required to shape the mesh screen 120 in FIG. 11 will equal the three-dimensional stability of the mesh implant formed with screen 120 in its final form.

FIG. 12 is a plan view of still another embodiment of the present invention and includes a grid section 122 of a form-fitting mesh implant for the fixation and immobilization of bone fragments and bridging of bone defects that is again formed of biocompatible metallic material having a plurality of plate sections 134 with an orifice 136 in each plate section for receiving a bone screw. Again, at least one arm 124 and 126 connects each two adjacent plate sections 134. Again, each of the arms 124 and 126 has a bend therein such that the arms 124 and 126 can be selectively compressed, stretched, and contoured without deformation of the bone screw orifice 136. It will be noted in this case that all of the rows of arms 124 are all bent in the same direction and that all of the column

arms 126 are also bent in the same direction. This construction allows the mesh implant to be more readily compressed or stretched in any given direction. For instance, if the entire mesh implant section 122 shown in FIG. 12 needed to be compressed in the horizontal direction in FIG. 12, all of the arms 126 could be compressed all in the same direction. In like manner, if the mesh implant 122 needed to be compressed in the vertical direction, all of the arms 124, in either one row or in all rows, could be compressed. Thus with such construction, the mesh implant 122 can be readily shaped by compressing, stretching, and contouring in whatever direction is needed to form the shape needed for a particular bone configuration. It will be noted in FIG. 12 that the included angle of each of the arms 124 and 126 may be, for example, 120°. In like manner, the angle of the arm 124 and 126 to the horizontal or vertical as seen in FIG. 12 as it exits from the orifice plate may be, for example only, 30° or 60° as illustrated by the numerals 130,132. Orifices 136 have a sloping shoulder 138 so that the bone screws having a corresponding sloping shoulder have a minimum projection above the grid or mesh implant 122.

FIG. 13 is a cross-sectional view of the mesh implant 122 illustrating that the arms 126 are 0.3 millimetre in thickness, for example, the diameter of the upper portion of the orifice 136 is 1.55 millimetres while the diameter of the lower portion of the orifice is 1.2 millimetres, and the thickness of the orifice plate 134 is shown to be, for example only, 0.42 millimetre. The radius of an orifice plate 134 may be, for example only, 1.25 millimetres and the width of an arm may be, for example only, 0.3 millimetre. As those skilled in the art will appreciate, other size configurations could be used and the preceding explanation is for illustrative purposes only.

In a further embodiment, as shown in FIG. 14, orifice plate sections 140 and 142 are coupled together by an arm 144 having three sections and two bends rather than two sections and one bend as shown in the other embodiments. As those skilled in the art will appreciate other numbers of bends could be incorporated into the implant between orifice plate sections.

Finally, FIG. 15 discloses another embodiment of the present invention, namely, a single rectangular grid 146 formed by four orifice plates 148 coupled to arms 150.

Claims

1. A form-fitting implant for the fixation and immobilization of bone fragments and bridging of bone defects or gaps at one or more sites of a patient, the implant comprising a mesh of biocompatible metallic material having at least two plate sections (40,42) with an orifice (41) in each plate section for receiving a bone screw; and at least one arm (44) connecting the two plate sections, the arm having at least two arm sections connected at a bend (46) such that the arm can be selectively compressed, stretched, and contoured primarily by deformation at the bend to fix bone fragments in a particular anatomical shape.

2. An implant according to claim 1, wherein the arm has a first width at its junctions with the plate sections and a second smaller width (80) adjacent to the bend.

3. An implant according to claim 1 or claim 2, wherein the arm (44) has two straight sections connected at an angular bend (46).

4. An implant according to any one of the preceding claims, wherein the arm includes more than one bend (FIG. 14).

5. An implant according to any one of the preceding claims, wherein two parallel ones of the arms connect each of the plate sections to the same adjacent plate section (FIG. 11).

6. An implant according to any one of the preceding claims, which has a plurality of the plate sections forming a grid with an interior area and an exterior periphery; and four of the arms integrally formed with each plate section in the interior area, each arm connecting the plate section with an adjacent plate section (FIGS. 5,7,12).

7. An implant according to any one of claims 1 to 5, which has a plurality of the plate sections forming a grid with an interior area and an exterior periphery; and three of the arms integrally formed with each plate section in the interior area, each arm connecting the plate section with an adjacent plate section (FIG. 9).

8. An implant according to any one of claims 1 to 6, which has a plurality of the plate sections arranged in a lattice-like structure of rows and columns; with the arms connecting the plate sections in each row and the plate sections in each column; all of the arms connecting of plate sections in the rows being bent in the same direction and all of the arms connecting the plate sections in the columns being bent in the same direction (FIG. 12).

9. An implant according to any one of claims 1 to 5, including four of the plate sections for forming a rectangular grid; and four arms, wherein each of the arms is integrally formed with two of the plate sections to form the rectangular grid (FIG. 15).

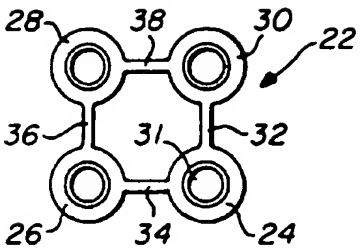

FIG. 2

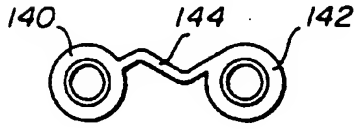

FIG. 14

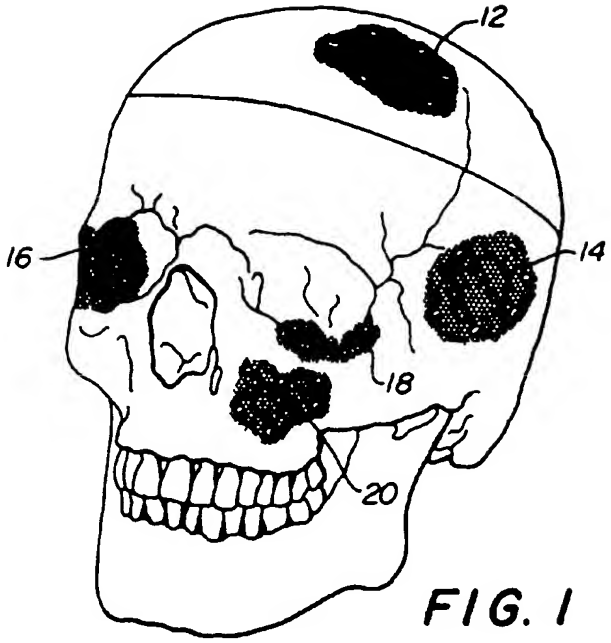

FIG. 1

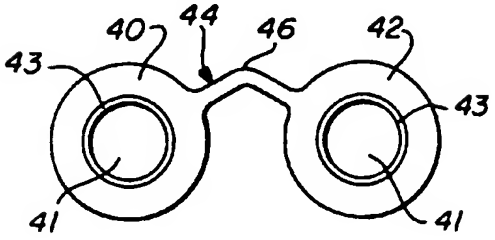

FIG. 3

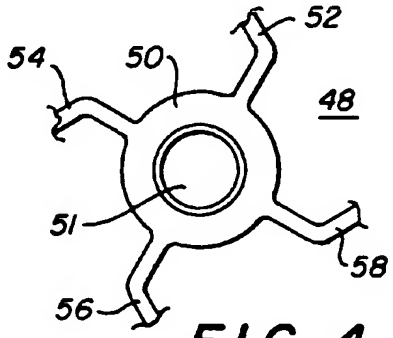

FIG. 4

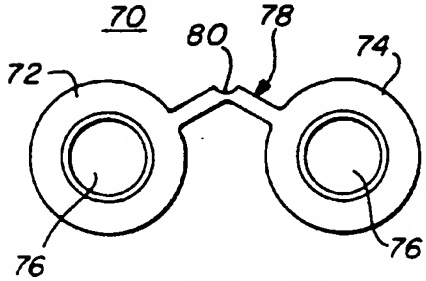

FIG. 6

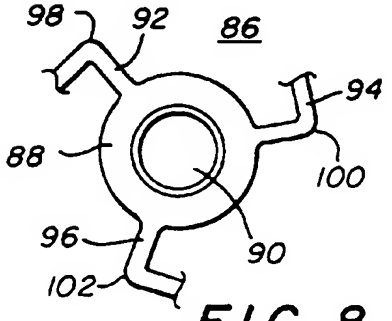

FIG. 8

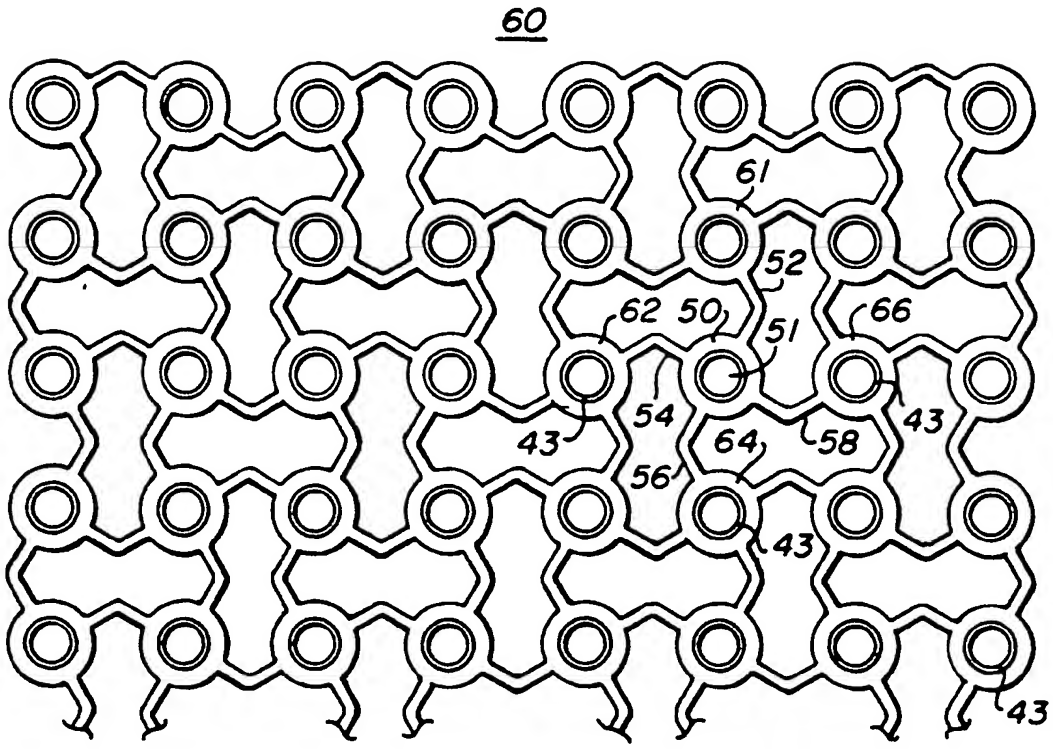

FIG. 5

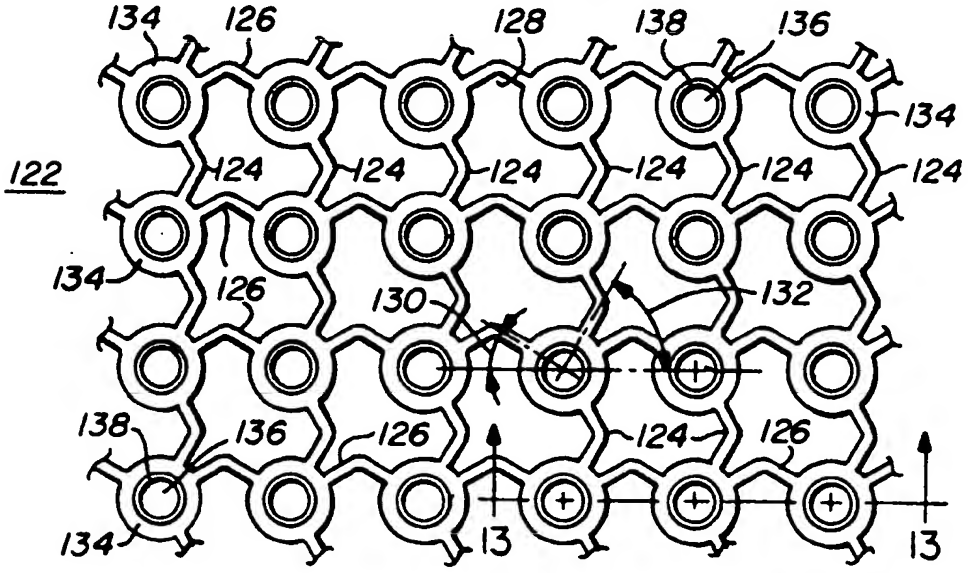

FIG. 12

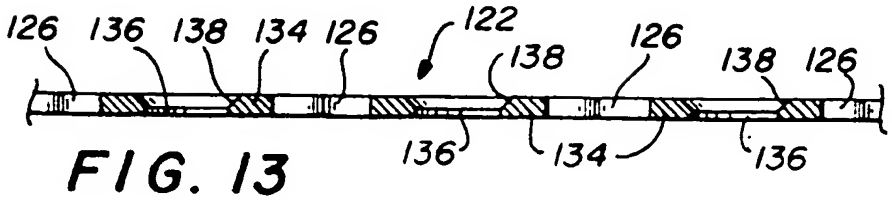

FIG. 13

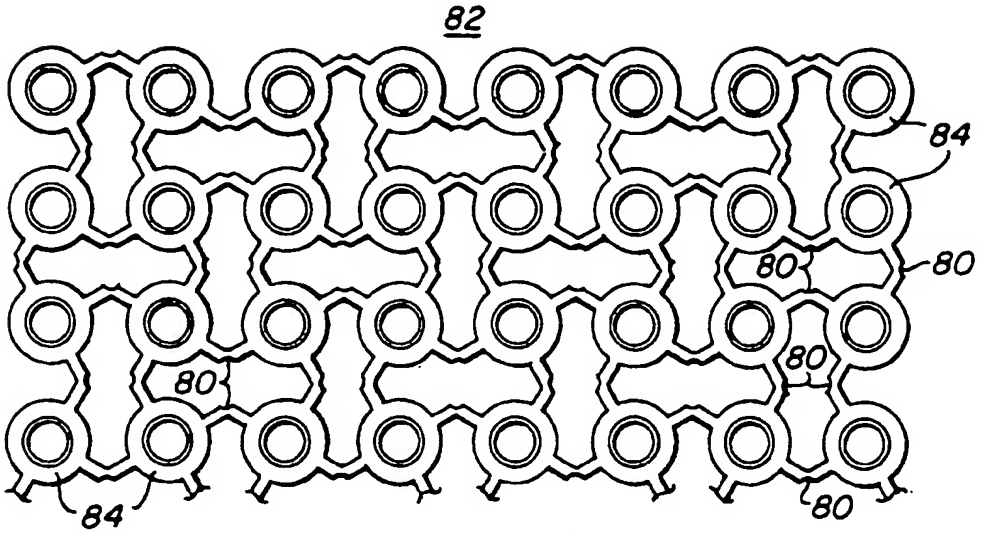

FIG. 7

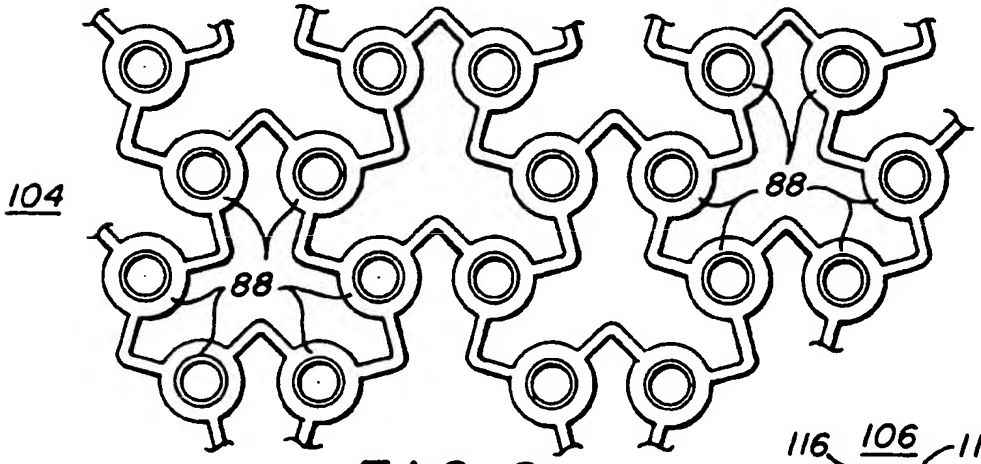

FIG. 9

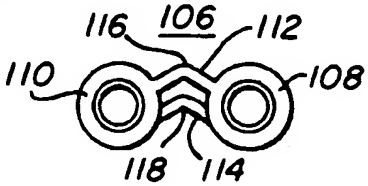

FIG. 10

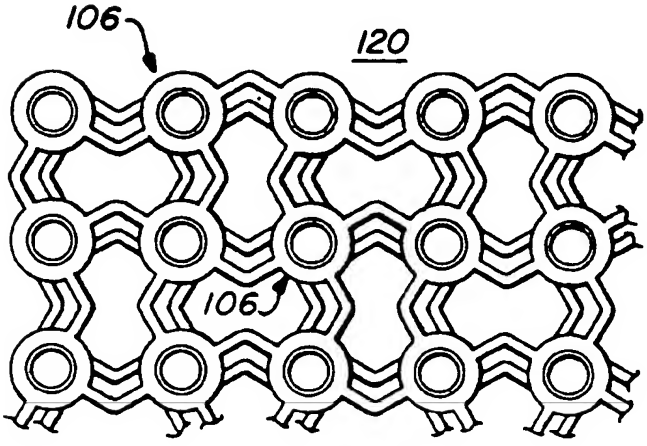

FIG. 11

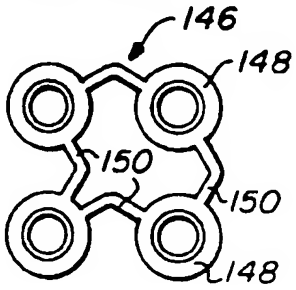

FIG. 15

European Patent Office

EUROPEAN SEARCH REPORT

Application Number EP 94307507.7

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 6)
Y	DE - A - 3 839 859 (BRISTOL MYERS) * Fig. 4,5,14,15; column 3, line 57 - column 4, line 2; column 5, lines 25-28, 40-68 * --	1,3,4, 6,9	A 61 B 17/68
Y	EP - A - 0 433 852 (D. LEIBINGER GMBH) * Totality, especially fig. 1-5; abstract; column 6, line 56 - column 8, line 27 * --	1,3,4, 6	
Y	US - A - 4 905 679 (F.H. MORGAN) * Totaltiy, especially fig. 7; column 7, lines 27-33 * --	9	
A	GB - A - 1 579 575 (ENGL. BIONECHANICS) * Totality * --	1-3,6, 7	TECHNICAL FIELDS SEARCHED (Int. Cl.6) A 61 B
A	EP - A - 0 291 632 (HOWMEDICA) * Fig. 3,4,6; abstract * ----	1	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
VIENNA	29-12-1994	LUDWIG

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P0401)